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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,047	04/15/2004	Steven Odrich	2755.025US1	7403

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
10/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,047	ODRICH, STEVEN	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 - 36* is/are pending in the application.

4a) Of the above claim(s) *13, 14, 18, 18, 19, 23 - 28, 32, 35, 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 12, 15, 17, 20 - 22, 29- 31, 33, 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/11/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of an exposed medication-discharging supply and one or more active agents in the form of a medicine configured for treatment of the eye in the reply filed on August 18, 2008 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11, 12, 15, 17, 20 – 22, 29 – 31, 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no indication in the application as originally filed to support for the presence of an exposed medication-discharging supply being included in the punctual plug. The Examiner was unable to find support for this limitation in the application as

originally filed. If Applicant is in disagreement with the Examiner regarding support for the amended claims, Applicant is respectfully requested to point to page and line number wherein support may be found for the instant invention.

4. Claims 22, 30, 31, 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims recite a time frame for sustained release of “at least about 3 months". The application as originally filed states that "A once-per 3 – 6 month visit to the eye doctor would be all that is needed” (¶ [0020] of the PGPub of the instant application). Therefore there is no support for the entire range of at least about 3 months which encompasses time frames of longer than 6 months; only a time frame of 3 – 6 months, as recited in the original specification is supported.

Claim Rejections - 35 USC § 112 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11, 12, 15, 17, 20 – 22, 29 – 31, 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention. It is unclear which end of the punctual plug is the distal and proximal end. “Proximal” and “distal” are not used in the specification, but support for these two parts can be inferred from the figures. Given that proximal means closer to the center, it seems that the proximal end of the device should be the portion of the device inserted fist into the punctum, while the distal portion remains outside the lacrimal punctum (such as the stopper, part 14, shown in figure 1. “Exposed” could mean exposed to the exterior surface, such as when not all of the device is inserted into the punctum, but this term could also be interpreted to mean that the medication discharging supply could be inside the punctum but not coated, for example, so that the medication discharging supply is exposed to the interior of the body. Claim 21 claim requires the exposed medication-discharging supply to be disposed on at least one external surface of the proximal end portion of the plug body. As “proximal”, “distal”, “exterior” and “external” is not present in the specification, what structure is being required by the claims is cannot be determined.

7. Claims 22 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims contain the limitation “at least about 3 months”. “At least” is a minima and all possible values above 3 months are encompassed. “About” indicates a range centered on the recited value. In this case, values both above and below 3 months. Therefore, what values are included in the range “at least about 3 months” cannot be determined.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 11, 12, 15, 17, 20 – 22, 29 – 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (US 3,949,750).

Freeman discloses a punctal plug by using the plug as a means to prevent drainage of lacrimal fluid from the eye or as a carrier vehicle for storing and delivering medication to eye (col 1, ln 8 – 14). The plug is impregnated with or otherwise acts as a carrier material for an ophthalmic medication (abstract). As can be seen in figures, particularly figures 2A and 2B, the plug can have a head region (part 28 or 28') and a lower portion (part 22 or 22') which is an inner stopper structure as recited in claim 33. In certain embodiments, the plugs (part 20 or 20'), particularly the head portion can be made of a porous material or otherwise configured to store and slowly dispense ophthalmic drugs to the eye as they are leached out by the lacrimal fluids (col 5, ln 8 – 14 and claim 4). Thus, Freeman discloses a punctual plug in which the head or body has a medication-discharging supply on an external or outer surface of the plug body and provides a sustained release of the active ingredient from the plug. As the medication leaves the device, the external surface of the device is an exposed

medication discharging supply. Alternatively, when the head portion of the device dispenses the medication, the head can be viewed as an external (outside the body) surface of the plug which acts as the medication discharging supply. The time course of release is not disclosed but the delivery of active ingredient over time is disclosed. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

10. Claims 11, 12, 15, 17, 21, 22, 29 – 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohan et al. (US 6,196,993).

Cohan et al. discloses ophthalmic inserts for the sustained release of medication to the eye comprising a body portion sized to pass through a lacrimal punctum with a collarete structure that sits on the exterior or the lacrimal punctum (abstract). A pore in the collarete allows for the exit of medication from the reservoir within the plug body (part 34; abstract). As can be seen in figure 6, a wick extension, a porous or absorbent material, extends from the reservoir to aid in medication release to the eye (col 5, ln 21 – 23; ln 27 – 30) and this part is a external (outside the body) surface of the medication discharging supply. The amount of drug that can be present in the insert, thereby extending the time frame over which the medication can be administered, can be

substantially increased by the inclusion of a reservoir extension, as shown in figure 5 (col 5, ln 11 – 20). This extension is external to (outside of) the plug body although. Part 28 can be included and shown in figure 3 to help secure the insert within the canaliculis (col 4, ln 45 – 48).

The length of time over which the drug can be administered is not disclosed, but particularly in view of the expandable reservoir that can be included in the device, there is no indication that the ophthalmic inserts disclosed by Cohan et al. do not meet the limitations regarding an administration time frame of at least about 3 months. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 11, 12, 15, 17, 20 – 22, 29 – 31, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (US 3,949,750) in view of Bhushan (PGPub 2004/0137068).

Freeman discloses a punctal plug by using the plug as a means to prevent drainage of lacrimal fluid from the eye or as a carrier vehicle for storing and delivering medication to eye (col 1, ln 8 – 14). The plug is impregnated with or otherwise acts as a carrier material for an ophthalmic medication (abstract). As can be seen in figures,

particularly figures 2A and 2B, the plug can have a head region (part 28 or 28') and a lower portion (part 22 or 22') which is an inner stopper structure as recited in claim 33. In certain embodiments, the plugs (part 20 or 20'), particularly the head portion can be made of a porous material or otherwise configured to store and slowly dispense ophthalmic drugs to the eye as they are leached out by the lacrimal fluids (col 5, ln 8 – 14 and claim 4). Thus, Freeman discloses a punctual plug in which the head or body has a medication-discharging supply on an external or outer surface of the plug body and provides a sustained release of the active ingredient from the plug. As the medication leaves the device, the external surface of the device is an exposed medication discharging supply. Alternatively, when the head portion of the device dispenses the medication, the head can be viewed as an external (outside the body) surface of the plug which acts as the medication discharging supply.

Freeman does not explicitly disclose the length of time over which drug delivery takes place.

Bhushan discloses an ophthalmic formulation for treatment of ocular conditions such as age-related macular degeneration (abstract). These formulations are administered multiple times a day for a time period of more than 1 year (¶ [0082]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a punctual plug, which Freeman teaches can have a head region that releases an ophthalmic active ingredient over time, to prepare such a plug so that the drug is released over a time period of many months, a time frame of

treatment that is employed in the treatment of ocular conditions by administration of a formulation directly to the eye, as taught by Bhushan.

15. Claims 11, 12, 15, 17, 21, 22, 29 – 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohan et al. (US 6,196,993) in view of Bhushan (PGPub 2004/0137068).

Cohan et al. discloses ophthalmic inserts for the sustained release of medication to the eye comprising a body portion sized to pass through a lacrimal punctum with a collarete structure that sits on the exterior or the lacrimal punctum (abstract). A pore in the collarete allows for the exit of medication from the reservoir within the plug body (part 34; abstract). As can be seen in figure 6, a wick extension, a porous or absorbent material, extends from the reservoir to aid in medication release to the eye (col 5, ln 21 – 23; ln 27 – 30) and this part is a external (outside the body) surface of the medication discharging supply. The amount of drug that can be present in the insert, thereby extending the time frame over which the medication can be administered, can be substantially increased by the inclusion of a reservoir extension, as shown in figure 5 (col 5, ln 11 – 20). This extension is external to (outside of) the plug body although. Part 28 can be included and shown in figure 3 to help secure the insert within the canaliculis (col 4, ln 45 – 48).

Cohan et al. does not explicitly disclose the length of time over which drug delivery takes place.

Bhushan discloses an ophthalmic formulation for treatment of ocular conditions such as age-related macular degeneration (abstract). These formulations are administered multiple times a day for a time period of more than 1 year (¶ [0082]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a punctual plug with a reservoir as taught by Cohan et al. and to prepare such a plug so that the drug is released over a time period of many months, a time frame of treatment that is employed in the treatment of ocular conditions by administration of a formulation directly to the eye, as taught by Bhushan.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW